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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/539,372

06/16/2005

Scott Martin Sheehan

X15072

4278

25885

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03/06/2008

ELI LILLY & COMPANY

PATENT DIVISION

P.O. BOX 6288

INDIANAPOLIS, IN 46206-6288

EXAMINER

BERNHARDT, EMILY B

ART UNIT

PAPER NUMBER

1624

NOTIFICATION DATE

DELIVERY MODE

03/06/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/539,372	<b>Applicant(s)</b> SHEEHAN ET AL.	
	<b>Examiner</b> Emily Bernhardt	<b>Art Unit</b> 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-15,18-23,26 and 27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,7,9,13-15,18 and 20 is/are rejected.
- 7) ☒ Claim(s) 2,4-6,8,10-12,19,23 and 27 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/16/05</u> .   | 6) <input type="checkbox"/> Other: _____                          |

Applicant's election without traverse of Group II in the reply filed on 2/8/08 is acknowledged. While the claims have been amended to the elected subject matter, the additional processes recited in claim 21 are held withdrawn pending allowable compound claims consistent with the PTO's rejoinder policy.

Claims 22 and 23 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims are directed to starting materials and thus reliance on variables set forth in claim 1 is improper as the claim does not include said compounds.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 7, 9, 13-15, 18, 20, 21 and 26 are rejected under 35 U.S.C. 103(a)

as being unpatentable over Mashkovsky (NPL article and EP'256).

Mashkovsky in both references teaches very similar compounds to that claimed herein that possess antiarrhythmic activity and are thus useful for treating ischemic heart disease which is covered by applicants' method claim. See formula I on p.2 and uses on 2 and 4. Closest compound in EP'256 is example 3 which differs from that claimed herein in having a Br vs instant Cl at X<sup>4</sup>. Note that Mashkovsky teaches all types of halos at this position as can be seen in the definition for R1 on p.2. The Mashkovsky article (provided as an English translation) additionally describes a compound, namely compound 20 in Table 1 on p.5 which differs from that claimed herein in being a position isomer that is having 2,3 dichlorophenyl vs. instant 3,4. Thus the compounds are position isomers. Position isomers are not deemed patentably distinct absent evidence of superior, and unexpected results. See In re Crounse 150 USPQ 554; Ex parte Engelhardt 208 USPQ 343 regarding position isomerism. Additionally, the process of claim 21 is taught as the sole process to make compounds in EP'256. See reaction scheme involving formula II and III on pp.2-3.

Thus it would have been obvious to one skilled in the art at the time the invention was made to expect instant 4-Cl phenyl and 3,4

dichlorophenyl derivatives to also possess the uses taught by the applied art in view of the close structural similarity as well as equivalency teaching outlined above and their preparation via the instant process an obvious expedient.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 22 is rejected under 35 U.S.C. 102(b) as being anticipated by Mashkovsky (EP'256). The product of example 3 discussed above is described as being made in the same manner as example 1 which uses the appropriate starting material of formula II. Thus to make example 3 the corresponding piperidin-1-yl compound was necessarily used and thus is implicitly described in the EP publication.

Claims 2,4-6,8,10-12,19,23 and 27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and

any intervening claims. The structural features embraced in these claims is not particularly taught or suggested by the closest art applied above.

Applicants' IDS filed 6/16/05 has been considered. While refs. B1 and B5 were not provided by the International Bureau they were available online.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is 571-272-0664.

If attempts to reach the examiner by telephone are unsuccessful, the acting supervisor for AU 1624, James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily Bernhardt/  
Primary Examiner, Art Unit  
1624

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